



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/547,999

09/07/2006

Daniel Portnoy

BERK-017CIP

6366

24353 7590 10/15/2008  
BOZICEVIC, FIELD & FRANCIS LLP  
1900 UNIVERSITY AVENUE  
SUITE 200  
EAST PALO ALTO, CA 94303

EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

10/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/547,999	<b>Applicant(s)</b> PORTNOY ET AL.	
	<b>Examiner</b> Patricia A. Duffy	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-34 is/are pending in the application.
- 4a) Of the above claim(s) 16-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 15 and 25-32 is/are rejected.
- 7) ☒ Claim(s) 33 and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **RESPONSE TO AMENDMENT**

The amendment filed 7-3-08 has been entered into the record. Claims 1-13 have been cancelled. Claims 14-34 are pending. Claims 14, 15 and 25-34 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

#### ***Election/Restrictions***

This application contains claims 16-24 drawn to an invention nonelected without traverse. A complete reply to the final rejection must include cancellation of nonelected claims.

#### ***Rejections Withdrawn***

The rejection of claims 14, 15, 25, 26, 27, 28, 29, 30, 31, 33 and 34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on the amendment to the claims.

The rejection of claims 14, 25, 29, 30, 31 and 32 under 35 U.S.C. 102(b) as being anticipated by Shen et al (Proc. Nat. Acad. Sci, USA, 92:3987-3991, April 1995; of record on 1449) is withdrawn based on the amendment to the claims.

The rejection of claims 14, 15, 25, 29, 30, 31 and 32 under 35 U.S.C. 103(a) as being unpatentable over Frankel et al (US Patent No. 6,099,848, issued August 8, 2000) is withdrawn based on the amendment to the claims.

#### ***Rejections Maintained***

Claim 14, 15, 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frankel et al (US Patent No. 6,099,848, issued August 8, 2000) in view of Frazao et al (WO 99/07861, published 18 February 1999) and Loessner et al (Molecular Microbiology,

Art Unit: 1645

35(2):324-340, 2000) is maintained for reasons made of record in the Office Action mailed 4-3-08.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that the office as not set for a "credible" reason to combine all three references. This is not persuasive, Frazao et al specifically teaches "The scope of the present invention is not restricted to mycobacteria and is applicable to other bacteria, such as: *Samonella* spp., *Vibrio*, spp., *Shigella* spp., *Lactobacillus* spp., *Streptomyces* spp., *Corynebacterium* spp. *Listeria* spp.." (page 7, lines 4-7). This is not persuasive because the office has recited a credible reason for combination and the art as combines merely substitutes one known element with the same function for another. Furthermore, the art specifically indicates that they contemplate similar plasmids targeted to other genera. Applicants argue that integrase attachment sites are different from homologous recombination. This is simply not true, because the integrase attachment sites provide for homologous recombination into the genome. These are not separate concepts in the art. In fact, as described by the cited art the integrase sites allow site-specific homologous recombination and the use of phage attachment sites for site-specific homologous recombination has been known for over 10 years. Credibility is not an issue with respect to motivation. The skill in the recombinant vector technology is very high and the references as combined provide for a reasonable expectation of success. Applicants argue no reasonable expectation of success to remove elements from their known sequence and place in a vector would function the same. This is not persuasive because the similar elements from a variety of phages have been used in site-specific integretave plasmid vector construction in the art. It would therefore have been reasonable to expect that the same would be true for the sequences of Loessner et al phage as particularly suggested by Frazao et al. Applicants argue that since one could not separate the core attP sequence from upstream and downstream regions in lambda there is no expectation that one could separate the attP sequences from the Loessner et al listeriphage 118.

This is not persuasive because there is a direct teaching in Frazao et al that contradicts the teaching of the art. Applicants argue that the separation of bacteriophage attP sites in listeria is an unexpected result. This is not persuasive because the teaching of Frazao et al teach that bacteriophage attP sites could be separate from integrase genes.

The rejection is maintained.

### ***Status of Claims***

Claims 14, 15, 25-32 stand rejected. Claims 16-24 are withdrawn from consideration.

Claims 33 and 34 are objected to as depending from a rejected base claim.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisors, Shanon Foley can be reached on 571-272-0898 or Robert Mondesi at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/

Patricia A. Duffy, Ph.D.

Primary Examiner

Art Unit 1645